

CLAIMS:

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I claim:

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GROUP 1600

1. A method for determining the presence of HIV antibodies in a test sample, wherein the said method comprises the steps of preparing a test means by successfully impregnating a solid, absorbant, carrier matrix capable of transporting a liquid by capillary action, with a buffer, anti-IgG (used to form a control line), anti-HIV antigen conjugated to microparticles, anti-IgG conjugated to microparticles, and anti-HIV (used to form a assay line) that produces a detectable response to the presence or absence of anti-HIV at the assay and control lines on said means, drying said test means, placing test sample on test means, and determining the quantity of anti-HIV in said test sample by comparing the relative intensity of the assay line produced to the relative intensity of the control line.

2. The method according to claim 1 wherein the antibody to anti-HIV can be selected from the group consisting of anti-HIV (I or II), anti-anti-HIV, anti-Human IgG, IgA, IgD, IgE, or IgM.

3. The method according to claim 1 wherein the anti-HIV antigen can be selected from the group consisting of HIV antigens I, HIV antigen II, or recombinant anti-HIV antigen.

4. The method according to claim 1 in which the buffer can be selected from the group consisting of citrate, hepes, tris (trizma), taps, popso, tes, pipes, mopso, tricine, mops, mes, bicine, bes, caps, epps, dipso, ches, capso, ampso, aces, ada, bis-tris-propane, tapso, heppso, tea, amp, phosphate, phthalate, succinate, hydrochloric acid, sulfuric acid, nitric acid, acetic acid, sodium hydroxide, and potassium hydroxide.

4. The method according to claim 1 wherein the test sample can be any biological fluid can be selected from the group consisting of urine, serum, whole blood, saliva, cerebral spinal fluid, gastric contents, and extracts of hair or sweat.

6. The method according to claim 1 wherein the microparticle is a suitable material that will form a solid platform or substrate for the covalent attachment of antibodies or antigens and can be selected from the group consisting of colored particles, rubber, latex, plastics, synthetic solids, or metals.

7. A method according to the method of claim 1 employing a dry chemistry test strip (DCID) method to measure the anti-HIV concentration in a test sample, the method comprising the steps of;

(a) preparing a test means by successively impregnating an absorbent carrier matrix with reagent solutions,

(b) drying said test means,

(c) dipping completed test means into test sample,

(d) and determining the quantity of anti-HIV present in said test sample by comparing the relative intensity of the color produced by the reaction to a color chart with color blocks referenced to specific concentrations of anti-HIV wherein the reagent solutions are composed of buffer, beta-Galactosidase/HIV antigen and 5-bromo-6-chloro-3-indoxyl-beta-D-galactopyranoside.

9. The method according to claim 1 for determining the anti-HIV concentration of a test sample wherein creatinine, cystatin C, or specific gravity concentration can be used to normalize the sample for accurate determination of anti-HIV.

10. The method according to claim 9 wherein the calculation to normalize the anti-HIV concentration requires that it be divided by the creatinine, cystatin C, or specific

gravity concentration of the same test sample thereby yielding the anti-HIV to creatinine, cystatin C, or specific gravity ratio.

11. The method according to claim 7 wherein the buffer can be selected from the group consisting of citrate, hepes, tris (trizma), taps, popso, tes, mopso, tricine, mops, mes, bicine, hes, caps, epps, dipso, ches, capso, ampso, aacs, ada, bis-tris-propane, tapso, heppso, tea, amp, phosphate, phthalate, succinate, hydrochloric acid, sulfuric acid, nitric acid, acetic acid, sodium hydroxide, and potassium hydroxide.

12. The method according to claim 7 wherein the beta-Galactosidase can be selected from the group consisting of matched pairs beta-Cellobiosidase and cellobioside beta-D-Cellobiosidase and 5-Bromo-4-chloro-3-indoxyl-beta-D-cellobioside, beta-Cellobiosidase and 5-Bromo-6-chloro-3-indoxyl-beta-D-cellobioside, beta-Cellobiosidase and 4-Nitrophenyl-beta-D-cellobioside, beta-Cellobiosidase and 1-Naphthyl-cellobioside, beta-Cellobiosidase and 4-Methylumbelliferyl-beta-D-cellobioside.

13. The method according to claim 7 wherein the Galactosidase can be selected from the group consisting of Arabinosidase, Fucosidase, Galactosaminidase, Glucosaminidase, Glucosidase, Glucuronidase, Lactosidase, Maltosidase, Mannosidase, and Xylosidase and their corresponding substrates, Arabinopyranoside, Fucopyranoside, Galactosaminide, Glucosaminide, Glucopyranoside, Glucuronic acid, Lactopyranoside, Maltopyranoside, Mannopyranoside, and Xylopyranoside and may be bound to each of the following color indicator groups: 5-Bromo-4-chloro-3-indoxyl, 5-Bromo-6-chloro-3-indoxyl, 6-chloro-3-indoxyl, 5-Bromo-3-indoxyl, 5-Iodo-3-indoxyl, 3-indoxyl, 2-(6-Bromonaphthyl), 6-Fluoro-3-indoxyl 2-Nitrophenyl, 4-Nitrophenyl, 1-Naphthyl, Naphthyl AS-BI, 2-Nitrophenyl-N-acetyl, 4-Nitrophenyl-N-acetyl, and 4-Methylumbelliferyl moieties.

14. The method according to claim 7 wherein the Galactosidase can be selected

from the group consisting of carboxyl esterase, cholesterol esterase, sulfatases, and phosphatases.

15. The method according to claim 7 wherein the enzyme beta-Galactosidase conjugated to the HIV antigen can be selected from the grouped pairs consisting of carboxyl esterase and 6-chloro-3-indoxyl butyrate, and aryl sulfatase and 5-bromo-4-chloro-3-indoxyl sulfate, and alkaline phosphatase and 2-naphthyl phosphate.

16. The method according to claim 7 wherein the enzyme conjugated to the HIV antigen can be selected from the group consisting of dehydrogenase, oxidase, hydroxylase, or oxidoreductase.